

# IRBs and Psychological Science: Ensuring a Collaborative Relationship

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## Abstract

*Institutional Review Boards (IRBs) are federally-mandated, locally-administered groups charged with evaluating risks and benefits of human participant research at their institution. To a greater or lesser extent, risks and potential benefits exist in virtually any research with human participants, including research in the behavioral/social sciences. Federal law and APA standards require IRB review of all human participant research projects. IRB review and approval will likely bring an investigator into contact with two inter-related groups: the IRB and the professional staff that administers IRB activities. Due to a variety of factors, including increased IRB and faculty workload and enhanced federal oversight, the potential for conflict among IRB members, IRB administrators, and investigators may be great. Indeed, anecdotal evidence suggests that this potential for conflict may be particularly high for behavioral scientists, and that dissatisfaction with IRB review may jeopardize compliance with federal regulations, research participant protection, and research itself. The purpose of this paper is to suggest specific strategies that IRB members, IRB administrators, and investigators can use to avoid potential conflict and facilitate human research participant protection. We contend that when these groups understand and face these responsibilities collaboratively, conflict will be minimized and safe, ethical, high quality research will flourish.*

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Institutional Review Boards (IRBs) are federally-mandated, locally-administered groups charged with evaluating human participant research. IRBs, and human participant research in general, have come under increased scrutiny by legislators, regulators, the media, and the public, in part because of recent events where research participation resulted in harm to some participants (see Beh, 2002 and Oakes, 2002). At many institutions, this increased scrutiny has had a tremendous impact on the IRB review process. For example, IRB members are required to understand increasingly complex federal and state regulations when evaluating research protocols in the biomedical, behavioral, and social sciences. IRB administrators are required to oversee the training of local investigators and IRB members, and to process large numbers of research protocols submitted for local IRB review. Investigators are often required to describe even the most unlikely research risks in unprecedented detail, and use increasingly complex submission forms and procedures when preparing protocols for IRB review. Not surprisingly, these growing requirements have increased the potential for conflict among IRB members, IRB administrators, and investigators. For example, the potential for conflict arises between:

- IRBs and administrators, when IRB members are presented with ever-increasing number of protocols for review.
- administrators and investigators, when submission procedures change frequently to comply with changes in federal or institutional policy.
- investigators and IRBs, when IRB review is seen as a challenge to independent research.

These and other potential conflicts can be damaging to all, especially if they limit thorough review, compliance with federal law, or detailed description of risks and safeguards. For example, relative to psychology faculty who are satisfied with IRB functioning, psychology faculty who are dissatisfied are less likely to comply with IRB policies and procedures (Liddle & Brazelton, 1996). In extreme cases, conflict among these three groups may jeopardize an institution's ability to conduct safe, ethical, high quality research. In the sections below, we review briefly how IRBs are mandated and organized, and then present strategies for reducing conflict in human participant research.

## IRBs are Federally Mandated

Federal regulations that pertain to the IRB are specified in Title 45 Code of Federal Regulations Part 46 (45 CFR 46) and Title 21 Code of Federal Regulations Parts 50 and 56 (21 CFR 50 and 56). Individuals who submit research proposals to an IRB should be aware that federal regulations frame all IRB action. The ethical foundations for this regulatory framework are contained in the report of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research entitled, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Office for Protection from Research Risks, OPRR, 1979). As described in these documents, IRBs consider a variety of important issues, including participant safety and freedom from coercion, and the potential benefits and risks of research. Potential research benefits include improvement of physical and mental health, and knowledge that contributes to the welfare of society (OPRR, 1993). Risks in research include physical, psychological, social, or economic harms, invasion of privacy, and violations of certain basic human rights (OPRR, 1979). To a greater or lesser extent, these risks and potential benefits exist in virtually any research with human participants, including psychological research. Thus, members of the American Psychological Association (APA) and similar professional societies are expected to conduct human participant research in strict adherence to applicable federal laws and regulations, which includes prior review and approval by an IRB (APA, 2002).

## IRBs Include Scientists and Non-scientists

IRBs are made up of a panel of reviewers constituted according to the rules set forth in the federal regulations (The Common Rule)<sup>1</sup>. An IRB usually includes individuals drawn from the following groups: (1) Faculty affiliated with the institution representing diverse academic disciplines that typically engage in research with human participants; (2) Non-scientist faculty affiliated with the institution; (3) Community representatives with no formal institutional affiliation whose role is to represent the interests of the community and to bring an independent perspective; and (4) If the IRB typically reviews research with prisoners, community representatives who have the sole responsibility to ensure that rights of prisoners are protected (for example, a public defender or a representative of a prisoner advocacy group). Non-scientist members bring an important perspective to the IRB review process, as they may advocate the views of potential research participants more effectively than may scientist members (e.g., Porter, 1987; Porter, 1986).

## IRBs are Locally Administered

The administrative staff for the IRB at many institutions consists of paid professionals who write operating procedures, handle correspondence with relevant federal agencies, process applications for review, request periodic progress reports from researchers, conduct training for researchers and IRB members, and generally provide support services needed for the oversight of research at the local, institutional level. Researchers should be aware that the IRB, *not the professional staff*, makes final decisions regarding a research project that has been submitted for consideration. Thus, the IRB and the professional staff have differing roles and responsibilities, and their relationship with researchers will therefore differ.

## Conflict Potential Among IRBs, Administrators, and Investigators

Increased scrutiny of human participant research has intensified pressures on IRBs, administrators, and investigators. Intense pressure can lead to increased potential for conflict. Anecdotal evidence suggests that possibility of conflict with IRBs and IRB administrators may be high for some behavioral scientists (e.g., Oakes, 2002; Council, Smith, Kaster-Bundgaard, & Gladue, 1999). These scientists cite the minimal risks associated with their research methods, such as questionnaires, item recall, or stimulus response. For these investigators, IRB review may be seen as a hindrance that adds little to research participant protection (e.g., Brinthaup, 2002; Schmidt & Meara, 1996). Further, the administrative burdens of investigator training, IRB submission, and follow-up reporting may impose seemingly overwhelming demands on already over-extended faculty.

IRBs, IRB administrators, and investigators can and should work collaboratively to reduce conflict potential. For example, IRBs can use the latitude provided in federal regulations to maximize participant protections while minimizing investigators' regulatory burden. IRB administrators can tailor training and review procedures to meet investigator and IRB needs. Investigators can work with IRB members to communicate research-related issues and to understand and address mandated IRB processes and procedures and specific IRB concerns. In sum, IRB members, IRB administrators, and investigators each play a role in protecting research participants within an institutional framework that removes impediments to quality research while ensuring compliance with applicable regulations. The purpose of this paper is to suggest specific strategies that investigators, IRB members, and IRB

<sup>1</sup> Sub-part A, of Title 45 Code of Federal Regulations, Part 46 (45 CFR 46), which specifies the basic Department of Health and Human Services policy for the protection of human research participants, was also adopted by 14 other federal agencies, the Central Intelligence Agency, and the Office of Science and Technology Policy and is usually referred to as The Common Rule.

administrators can use to avoid conflict and facilitate human research participant protection and high quality research.

## **IRBs, IRB Administrators, and Investigators: A Collaboration**

In this section, we propose strategies that emphasize a collaborative relationship among the IRB, IRB administrators, and investigators, and that involve responsibilities for each group. We begin by describing the most salient responsibilities for IRB members and IRB administrators, and then elaborate the responsibilities of investigators. We contend that when these groups understand and face these responsibilities collaboratively, conflict will be minimized and safe, ethical, high quality research will flourish.

### **Responsibilities of IRBs**

Individual IRB members and the IRB as a group have a variety of essential responsibilities that can be challenging. Delineating these challenges may help IRBs understand their role in facilitating safe and ethical research and help administrators and investigators appreciate the knowledge and thought that goes into IRB deliberations. IRB responsibilities include knowing and applying the rules, and maintaining open communication with administrators and researchers.

### **Knowing the Rules**

IRB members are most effective when they are conversant with the federal rules and regulations, as well as the underlying ethical principles that govern the conduct of research with human participants. Effective IRB members are also familiar with their own institutional policies and procedures, all of which affect deliberations and decisions regarding proposed research. Furthermore, effective IRB members are acquainted with the current guidance from federal regulatory agencies and emerging human research protection issues unique to behavioral, social, and/or biomedical research.

Knowing the rules is particularly important for IRBs faced with a research proposal outside their area of collective expertise; the regulations provide for a solution to this understandable challenge. The notion that every IRB has the expertise to review every proposal may be untenable in today's environment: the average number of IRB members at major research universities is 16, and these IRB members review an average of 297 research proposals each year (some review over 1000; Hayes et al., 1995). Many research institutions handle this issue by using multiple IRBs, (e.g., one focusing on biomedical and another on behavioral research; Hayes et al., 1995). As many IRB

members are aware, federal regulations make clear that an IRB must have the "... professional competence necessary to review specific research activities ...", and that an IRB may invite input from "... individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB" [45 CFR 46.107 (a) and (f)]. Thus, the regulations suggest that an effective IRB recognizes the research areas in which it is strong, and, when reviewing proposals from other areas, invites input from individuals with relevant expertise. The regulations make clear that respect for an IRB's advice and counsel is likely promoted when review is based on collective experience and expertise.

A complete knowledge of federal rules and institutional policies, and the ability to operationalize this knowledge when reviewing research protocols is essential for an IRB to be successful and respected. Equally important is an appreciation that most rules are open to interpretation, and can change with experience (e.g., Rosnow, 1997). Thus, effective IRB members are able to appreciate and learn from differing viewpoints within and outside IRB meetings. We suggest that openness to differing viewpoints, the ability to adapt standards based on these viewpoints, and a willingness to apply viewpoints and standards while maximizing participant protection within a research context are components of a successful collaboration.

### **Applying the Rules**

The federal regulations that govern IRBs provide a foundation on which an IRB can build and adapt its policies. IRBs interested in working collaboratively to facilitate safe, ethical, high quality research are cognizant of the latitude provided by the regulations. For example, under certain conditions, IRBs may waive written documentation of informed consent or particular elements of the consent document, and can also approve studies that use deception, or approve the use of financial incentives for participation, as illustrated in published psychological studies (e.g., Tiedens & Fragale, 2003; Phillips, Douthitt, & Hyland, 2001; Gire & Eissenberg, 2000). In essence, IRBs are obligated to interpret regulations in a manner consistent with the local environment, understanding that local environments differ substantially from each other and even differ across time. These differences mean that the application of regulations is not done automatically or mechanically, but is guided by thoughtful consideration of the spirit or purpose of the regulation as it relates to a specific research project.

### **Maintaining Open Communication**

An effective IRB engages in open and collegial exchange of information with investigators. Communication between investigators and the board as a whole, and/or be-



tween investigators and individual board members serving as reviewers, are consistent with federal regulations and should be encouraged. When possible, an investigator can be given the opportunity to address sources of confusion before the meeting at which his/her protocol will be reviewed. Because some concerns may be raised and clarified during the IRB meeting, steps can be taken to ensure that investigators are available to answer questions (e.g., by contacting the researcher by phone during the meeting or having the researcher physically present to answer questions during the meeting). Time permitting, the IRB may wish to invite a researcher to attend a meeting to present his/her research, or to discuss a particularly challenging issue. There may be practical limitations to these approaches because the entire board needs to have sufficient time to review revised documents before the meeting, but this type of communication may ultimately save time and resources for all involved, by reducing the length of the review process. Moreover, it serves to build a positive and collaborative relationship between IRBs and researchers.

### **Summary**

IRB members and the IRB as a whole are challenged by the need to keep abreast of federal and state regulations governing the conduct of human participant research and current guidance from federal regulatory agencies, apply regulations and guidelines fairly and practically, and maintain open lines of communication with IRB administrators and investigators. IRBs, IRB administrators, and investigators may work best as a team whose overall goal is to facilitate safe and ethical research with the greatest possible benefit and the least possible risk.

### **Responsibilities of IRB Administrators**

IRB administrators are generally the public face of the IRB, and interact with IRBs, researchers, and members of the general public, including the research participants, the press, and other influential groups. As such, IRB administrators might work best by maintaining a service orientation, facilitating timely, thorough, and complete reviews, providing clear and relevant protocol submission forms, communicating effectively with researchers, and also making available a variety of training opportunities for IRB members and research teams.

### **Maintaining a Service Orientation**

Put simply, the IRB administrative staff has an obligation to be helpful to investigators, without whom it would have no *raison d'être*. Being helpful to investigators is entirely consistent with an IRB administrator's primary responsibility to ensure the rights and welfare of human participants. Research participants are protected most effectively when IRB staff, IRB members, and researchers

work together to ensure their safe and ethical treatment. Being helpful includes ensuring that information regarding the process of obtaining IRB approval is contained in the written policies and procedures governing the operation of the local IRB, and that this information is readily available to investigators. This information, which should also outline investigator obligations and responsibilities, can be made available on a web site and/or distributed as a printed reference guide. Templates, checklists, and tip sheets can be provided to assist investigators in completing paperwork for submission. IRB administrators (and members) can provide telephone, e-mail, and personal consultations with investigators. Information regarding investigator responsibilities also can be disseminated through the approval letters sent to investigators. Thus, the professional staff could help the researchers understand and navigate the application process, thereby helping them comply with pertinent regulatory requirements.

### **Facilitating Timely, Thorough, and Complete Review**

Timely review is a key issue for psychologists (e.g., Liddle & Brazelton, 1996) and IRB administrators are in an excellent position to ensure that research applications are processed in a timely manner. For example, administrators may set goals for processing and review such that research protocols submitted for IRB review are processed (i.e., logged in and sent to a reviewer) within one week, and protocols are reviewed within five weeks of submission (three weeks for protocols that qualify for exempt or expedited status). Review goals may differ across institutions, but IRB administrators may be able to guide, evaluate, and reinforce timeliness in the review process.

Timeliness may be a particularly salient issue for psychological researchers who conduct research with undergraduate students. For example, a study involving students as research participants submitted in August, but not approved until mid-November, delays data collection until mid-January (because of holidays, final exams, etc.). This situation is detrimental to the productivity of an established researcher, but worse for a student gathering data for a thesis or dissertation, or a junior faculty member who undergoes periodic evaluation. The relevance of timely review has been highlighted in empirical studies of psychology faculty-IRB interactions. For example, a study of faculty at several research institutions showed that quick IRB review of proposals was the most commonly reported strength of an IRB, and slow review the most common complaint (Liddle & Brazelton, 1996; see also Ferraro et al., 1999). Interestingly, 23% of investigators who reported non-compliance with IRB policies indicated the reason was time: "I was in a hurry and could not afford the delay" (Liddle & Brazel-

ton, 1996; p. 5). Investigators' failure to comply with institutional policies and/or federal regulations can lead, in extreme cases, to suspension of all human participant research at the institution (Oakes, 2002). IRB administrators interested in identifying and reducing the influence of factors associated with non-compliance may want to work with investigators and IRB members to make sure that protocols are processed in a timely manner.

They may ask investigators to identify protocols that qualify for expedited review, so that a single qualified reviewer can review (and, where applicable, approve) the study, rather than waiting for the full board. Behavioral research is often a prime candidate for expedited review; although the federal regulations should be consulted to ensure that the study meets the criteria (see Federal Register, Volume 63, p. 60, 364 or Office for Human Research Protections, "Research that may be reviewed through an expedited procedure"; <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>).

IRB administrators have an outstanding opportunity to ensure that research proposals are reviewed by IRB members with the most relevant expertise. Thus, administrators may want to make sure that IRB members selected to review behavioral science or biomedical protocols are familiar with the relevant issues. Just as a cognitive scientist may not be the most appropriate reviewer for a trial investigating the efficacy of a novel surgical procedure, so a surgeon may not be the most appropriate for a cognitive science protocol. As noted, federal regulations encourage reviews by individuals with the appropriate expertise, even if those individuals are not regular members of the IRB.

Administrators can also encourage IRB members to provide complete, accurate and timely reviews, provide guidance on the regulations to IRB members as necessary to facilitate their review, and alert institutional officials if individual IRB member are having difficulty meeting their obligations to the university community. Institutional officials have the authority to remove IRB members who are not able to provide thorough, informed, and timely reviews.

### **Providing Clear and Relevant Protocol Submission Forms**

Clear, well-organized, and relevant IRB application forms are likely to elicit the most complete information from researchers. Eliciting complete information may sometimes necessitate different forms for different types of research. The information necessary for biomedical research protocols may be irrelevant for non-biomedical research, and vice versa. Thus, IRB administrators might construct application forms that extract appropriate information regarding research objectives, methodologies,

and outcome measures (Sieber & Baliyot, 1992). Where applicable, these forms might also ask investigators to indicate the type of review requested (exempt, expedited, or full board) and to provide a clear reason for their request. Forms that elicit relevant information may better allow IRB administrators help IRB members conduct comprehensive reviews and assess the criteria necessary for issuing IRB approval in a timely fashion.

### **Communicating Effectively with Investigators**

In order to make IRB procedures and requirements transparent to researchers, IRB administrators may want establish clear communication procedures. Ideally, there should be a variety of mechanisms through which researchers can access information about federal regulations, institutional policies and guidance, protocol submission and review procedures, IRB meeting dates and deadlines, research-related issues of local and national importance (e.g., proposed rule changes on the federal level), federal or institutional educational requirements and opportunities, and whom to contact for information or assistance. At some institutions, this type of communication involves diverse media, including web site updates, a newsletter column, and accessible IRB staff (Council et al., 1999).

Accessible staff can be an important component of IRB administration, and staff provide an opportunity for real dialogue between researchers and IRB administrators not possible through electronic communication. This dialogue might take place at both the individual and group levels. Open communication with individual researchers or research teams may be important for new researchers, researchers tackling particularly challenging issues, or researchers seeking to understand IRB requirements or submission and review processes.

For example, a challenge encountered by some scientists involves the requirement to obtain and document participants' informed consent (45 CFR 46.116 & 117). Sometimes research objectives are more consistent with verbal consent procedures, or enrolling children without parental permission. Disapproval of these requests suggests an opportunity for better communication between researchers and IRB. Researchers may be unaware that the regulations include specific provisions for IRBs to approve requests to alter or waive informed consent requirements.

For example, IRBs may waive the requirement to document in writing a participant's consent under certain conditions, if the signed consent document would represent a significant risk to participants.<sup>2</sup> Similarly, an IRB may waive the requirement to obtain signed consent if the research poses little risk and written consent would not

be required if the project did not involve research<sup>3</sup>. Thus, IRB administrators are in a position to advise investigators about the conditions necessary to obtain a waiver of the requirement to obtain written consent, and where appropriate, to make recommendations about how best to deal with the issue.

The provisions for waiving parental permission for research involving children often prove more challenging for researchers than do those regarding the documentation of consent. For example, in seeking guidance concerning a waiver of parental consent, a researcher might suggest a “passive consent” process. The IRB administrator processing the proposal might, however, note that “passive consent” is not a part of current regulations. In this situation, the administrator might provide the researcher with the applicable regulatory information and suggest seeking a waiver of parental permission that includes a procedure through which parents can opt their child out of the research.<sup>4</sup> This approach provides important information to the researcher about what is permissible within the regulatory framework, and puts the researcher in a better position to determine the best approach. Moreover, this approach allows the administrator to be a partner in problem-solving, where the shared goal is facilitating research while protecting research participants and complying with applicable regulations.

In addition to communication with individual researchers, group dialog is also important as it can allow for dissemination of new information by IRB administrators that may be of interest to a more general audience, and it also allow researchers to raise general concerns or challenges that they may be facing. Reaching out to a more general audience may be done through campus forums, campus town meetings, or by inviting an administrator to a departmental meeting, seminar, or other group gathering that is devoted to IRB issues. This dialog is important for dissemination of new information by IRB administrators, and for allowing researchers to discuss general concerns or challenges that they face. Reaching out to a general audience may be done through campus forums, campus town meetings, or by inviting an administrator to a departmental meeting, seminar, or other group gathering devoted to IRB issues. This dialogue also allows for sharing information and perspectives between IRB administrators and researchers. Researchers usually do not understand the IRB process or requirements as well as IRB administrators do, whereas IRB administrators may

not understand all the practical research-related issues, such as sampling, design, etc. Facilitating dialogue allows both parties to appreciate and understand the other’s concerns.

### **Providing Training Opportunities for IRB Members and Investigators**

Training is critical to reduce conflict and improve the working relationships among investigators, IRBs, and IRB administrators. Investigators who understand the ethical foundations of the federal regulations, the federal and state regulations governing human participant research, and the procedures used by their local IRB are less likely to see IRB decisions as inconsistent or arbitrary. In addition, investigators who understand the parameters within which IRBs operate can be more effective in presenting their research to the IRB, thereby minimizing difficulties in getting research approved. In turn, IRBs that are well grounded in the ethical foundations of the federal regulations and have a thorough understanding of the regulations may be more likely to use the latitude inherent in the regulations to tailor their review to the risks associated with a particular project. IRBs also may be more efficient and effective in their reviews if they understand clearly the scientific methodology and associated risks posed by certain research activities.

The notion that IRB policies and procedures develop over time suggests that IRB member training is an ongoing process. IRB administrators can take the lead in providing ongoing training opportunities. Periodical publications such as “Human Research Report: Protecting Researchers and Research Subjects” and “IRB: Ethics in Human Research” can be provided to IRB members. Brief training sessions conducted by IRB staff can be held during IRB meetings, and institutions may bring in outside trainers (e.g. a researcher who is also an IRB member at another institution) for extended training sessions. IRB administrators can encourage the use of consultants who provide a dual function (i.e., provide guidance on review of particular research activities and contribute to the general knowledge of IRB members). Broadcast e-mails to IRB members can be used to disseminate important guidance in a timely manner. Administrators might also encourage IRB members to attend regional and national meetings geared to human subject protection issues. IRB administrators can work with institutional officials to identify funds for IRB members to attend meetings or to bring in outside trainers.

<sup>2</sup> See HHS regulations at 45 CFR 46.117(c)(1): the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality.

<sup>3</sup> See HHS regulations at 45 CFR 46.117(c)(2): the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

<sup>4</sup> Such a procedure is clearly permissible for research that meets the conditions specified at 45 CFR 46.116(d).



IRB administrators should also support ongoing training opportunities for investigators. Administrators can request that their libraries carry publications geared to human research participant protection issues. A website with links to current guidance from OHRP and FDA, upcoming regional and national meetings, etc. should be available. In addition, joint workshops for investigators, IRB members, and IRB administrators can be held. These joint workshops may be particularly informative when these groups are all struggling with current interpretation of issues (e.g., third party consent) by federal regulatory agencies.

### **Summary**

IRB administrators are the interface between IRB members and investigators who seek IRB approval for their human participant research. Thus, these professional staff members are a critical part of the collaboration that we propose. When IRB administrators adopt a service orientation, and when IRB members and investigators work with IRB administrators to improve IRB services, research participants, researchers, and the research enterprise can benefit.

### **Responsibilities of Investigators**

Like IRB members and administrators, investigators who conduct research with human participants face many important challenges, and these challenges may increase along with increased regulatory oversight and public scrutiny of this work. The collaboration proposed here is a way to meet critical challenges, while maintaining and demonstrating a commitment to safe and ethical research. The investigators' role in the collaboration involves valuing research as a privilege, knowing the rules, appreciating comprehensive IRB review, planning ahead, and joining the process.

### **Valuing the Privilege of Conducting Research**

Investigators should remember that conducting research is a privilege (see Oakes, 2002). The opportunity to conduct research is formally granted by some combination of the researcher's institution (governmental or non-governmental), the federal government, and, where applicable, the funding agency. That this opportunity is a privilege and not a right is made most clear when the privilege is revoked, as it has been at several universities over the last 5 years (Oakes, 2002). Perhaps more important, research participants themselves endow the investigator with the privilege of conducting research. Regardless of the risks of a particular research study, participants put their trust in the principal investigator and his/her staff. This trust must be protected, through the application of basic ethical principles, including respect for persons, beneficence, and justice (OPRR, 1979). Along with their federally-

and/or institutionally-mandated roles, IRBs and IRB administrators are the formal bodies that speak for and protect the rights of research participants. In an important sense, when investigators collaborate with IRBs and IRB administrators, they are working with their participants to ensure the integrity of the research enterprise, and the ability of the investigator to exercise the privilege of conducting research.

### **Knowing the Rules**

Investigators benefit when they are familiar with the institutional policies and regulations that govern research with human participants. At most institutions this information is included in investigator manuals, which may be disseminated within the institution's research community, as printed copies and/or as web-based documents. A working knowledge of applicable policies and regulations enables investigators to better understand whether the proposed research activities meet the federal regulatory definitions of "research" and "human subjects." Although not all research falls under the authority of the IRB, most institutions require any research activity that meets both definitions contained in the Common Rule be submitted to the IRB for review. Thus, wide dissemination of basic regulatory information may ensure that investigators submit protocols for review prior to starting a research study. Furthermore, such knowledge equips the researcher to prepare more complete research protocols for IRB review, further facilitating the review process.

Investigators also benefit when they have a firm understanding of federal regulations governing human participant research and IRB review. Specifically, investigators may be able to save a great deal of time and effort if they understand the difference between exempt, expedited, and full board review, and know when to request which type (see Oakes, 2002 for an excellent summary). Of particular note for behavioral scientists, research that involves only "minimal risk" to participants likely qualifies for expedited review. Expedited review saves time for investigators and the IRB as a group, because a single member can approve (but not disapprove) a proposal. If an IRB does not make use of the expedited review process, an informed investigator might discuss with the IRB administrator the value to the IRB of providing this important service. Similarly, informed investigators can discuss with IRB administrators the value of ensuring that IRB membership includes expertise relevant to the review of particular research proposals, and the possibility of obtaining reviews from non-IRB members whenever necessary. These and other issues can be discussed in terms of improving IRB efficiency (e.g., expedited review of minimal risk protocols means more time for the full board to review non-minimal risk protocols; outside reviewers with

specific expertise help the IRB gauge risk and anticipated benefit accurately). Thus, informed investigators can be seen as partners in improving IRB procedures as well as research participant protections.

Investigators might also benefit from understanding current thinking among IRBs and federal regulatory agencies regarding behavioral and social science issues. For example, investigators might be encouraged to attend regional or national conferences geared to human research participant protection issues, because these conferences cover issues and concerns germane to behavioral and social science research.

### **Appreciating Comprehensive IRB Review**

As many investigators realize, comprehensive IRB review of a proposed research project can be a source of valuable feedback. IRB review of issues related to the rights and safety of participants is often appreciated, but investigators may become uncomfortable when IRBs consider issues related to research design, experimental method, or statistical analysis (e.g., Ferraro, Szigeti, Dawes, & Pan, 1999; Liddle & Brazelton, 1996). However, IRBs must always weigh the potential benefits of a study against the potential costs to the participants; and investigators would likely agree that there is little benefit to a project with a flawed research design, inappropriate experimental method, and/or improper data analysis plan. If investigators appreciate that design, method, and analysis can influence project benefit, then they can also appreciate why IRB are required to review these important issues when determining risk/benefit ratio (see, for example, Schmidt & Meara, 1996; Hayes et al., 1995). If a flawed project has no potential benefits, even minimal risks (such as emotional discomfort or breach of confidentiality) might tilt the ratio unfavorably (Schmidt & Meara, 1996). In such cases, the IRB might ask an investigator to clarify the appropriateness of the proposed design, method, and/or analysis plan, or to revisit these issues in a protocol revision. Such suggestions are part of the IRB review process (a majority of IRBs report that they review methodology; Hayes et al., 1995), just as they are commonplace in the review of grant applications and journal submissions.

### **Planning Ahead**

The proposed collaboration maintains that one of the primary responsibilities of IRB administrators is to be helpful to all investigators. Researchers too have a role to play in ensuring the success of this collaboration. One way that researchers can fulfill their obligations is by ensuring that their research time frame includes the time needed for thorough IRB review. Advance planning allows the researcher to prepare his/her protocol for efficient review, (e.g., by affording researchers time to consult with IRB

administrators and/or members about protocol specifics prior to submission), and also allows the IRB to process the application more efficiently (Schmidt & Meara, 1996). Thus, recognizing the time and resource constraints under which most IRBs function, and planning accordingly, reduces the burden and increases the benefit for both IRB and researcher.

### **Joining the Process**

The best way to help an IRB become responsive to the research needs of a particular discipline is for researchers in that discipline to become involved in the review process. Active researchers have an obligation to serve on local IRBs, and researchers should remember that IRB service is an excellent method of peer (and self) education (Gillespie, 1999). Many faculty may consider IRB service onerous, and suggest that their schedules are already full with departmental and other university service. These same ideas may occur to current IRB members as they review the protocols of their faculty colleagues. However, as more researchers join the process, they contribute to a decreased workload for individual IRB members.

There are also other ways to participate in IRB review, which include volunteering as an alternate or *ad hoc* reviewer, partnering with IRB administrators to host educational sessions, helping to review and improve IRB forms and procedures, and working with the IRB to find creative solutions to common challenges faced by behavioral/social science researchers.

### **Summary**

The increased public scrutiny of human participant research impacts all parties involved in the research enterprise. Accordingly, the proposed collaboration includes responsibilities for each party in order to facilitate research and protect rights and welfare of research participants. Researcher responsibilities include understanding the review process and having a realistic timetable, knowing the relevant federal policies and regulations, and becoming involved in local research oversight. Active participation by behavioral researchers in the review process is perhaps the most effective way to make the system responsive to the needs and circumstances unique to behavioral and social science research.

### **Responsibilities of Institutional Officials and Administration**

In addition to improving the working relationship among IRBs, IRB administrators, and researchers, there is also a need for other institutional officials to recognize and attend to the needs of social and behavioral science researchers. When an institution focuses on biomedical sci-



ences, enlightening the administration regarding regulatory issues or concerns pertaining to behavioral research may seem challenging. Meeting this challenge can bring enhanced support to the IRB, greater responsiveness from IRB administrators, and can facilitate the work of behavioral researchers in the institution.

One important goal for social and behavioral scientists involves gaining access to individuals with authority for their institutions' research programs. Investigators can identify appropriate institutional officials through a variety of mechanisms, depending on the type of institution. For an institution of higher education, research is overseen primarily by a Vice President or Vice Provost for Research, who serve typically as the signatory Institutional Official, but there may be others who also serve in this role. Often, each College also has an Associate Dean for Research or similar position. Hospital and medical facilities, such as the Veterans Affairs, typically have a different hierarchy but have individuals who oversee research conducted at the facility. Identifying the people who serve in these positions and establishing channels of communication with them can help bring greater appreciation of the needs of behavioral scientists. This greater appreciation is best gained when a researcher presents challenges in a constructive and positive manner, along with proposed solutions for meeting the challenges. Concerns that are presented with a clearly formulated and practical means of addressing them are often well received.

While IRB's are autonomous, there is considerable latitude with regard to a number of local policies regarding IRB issues. For example, institutional administration can influence IRB member tenure, application review forms, submission policies and deadlines. Because these issues involve the regulation of research, it is important that institutional administrators continually seek feedback from the diverse spectrum of researchers affected by them. Formal administrative mechanisms for ensuring researcher input into these processes may include establishment of an executive or advisory committee of researchers and systematic, periodic "customer satisfaction" surveys of the research community. If feedback is solicited and acted upon, institutional officials can facilitate a positive relationship among IRBs, IRB administrators, and researchers. They may also enhance the level of researcher participation in the process, and ultimately improve protections afforded to human research participants.

## Conclusion

IRBs represent the federal government and the local agencies involved in reviewing research and are responsible for protecting the rights and welfare of research participants at a particular institution. IRB administrators are responsible for organizing and maintaining the activi-

ties of the IRB and can serve an oversight role for IRB members and for investigators. Researchers are obligated to perform safe and ethical research and to minimize the risks and maximize the benefits of their science. These responsibilities and obligations can be met most effectively when IRBs, administrators, and researchers work collaboratively. At times, behavioral/psychological scientists may feel left out of the IRB process, or neglected by IRB administrators. When this feeling arises, it may be an indicator that greater collaboration is necessary. We hope that researchers will use the suggestions presented here to develop or enhance collaborative relationships with their IRB and IRB administrators. Perhaps more importantly, we hope that behavioral/psychological researchers will work to reduce conflict within the IRB process, secure in the knowledge that regardless of scientific discipline or role in the research process, the goal of all involved in the research enterprise is the same—to promote knowledge, to expand our understanding of each other and the issues that we face together, and to provide the best protection possible for those willing individuals who volunteer their time and trust to serve as research participants.

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